

REMARKS

Claims 1-7, 13-19 and 25-27 are rejected under 35 USC §103(a) over Allen et al. (6,334,856) in view of Kingsford (WO 01/36037). Claims 1 and 13, and the claims dependent therefrom, recite a plurality of microneedles having at least one elongate sharp edge which is oriented in the longitudinal direction and/or extends in a direction from the proximal end towards the distal end of the microneedle (emphasis added).

Allen is utilized to show a microneedle array comprising a plurality of microneedles with projections. Kingsford is used to show elements having an outer edge contour with sharp projections proximal to an end of the element. The projections are said to extend in a direction from the proximal end of the microneedle (citing Figs. 3A-5 and the entire reference).¹

Kingsford Fig. 3A illustrates barbs 20a, 20b. Applicants have provided an enlarged Fig. 3A for the Examiner's convenience. On the enlarged Fig. 3A, Applicants have drawn a line intercepting the tip of each of barbs 20a, 20b. This is shown as the red dashed line for the Examiner's convenience. The enlarged Fig. 3A shows the extensions of the barbs of Fig. 3A intercept neither the proximal end of the projecting element nor the distal end of the projecting element. Accordingly, the edge of the barbs are not (1) oriented in the longitudinal direction, cannot extend in a direction (2) from the proximal end of the projection (3) or towards the distal end of the projection. Thus, three limitations recited in independent claim 1 and at least two limitations recited in independent claim 13 are not met by the rejecting combination.

Applicants have further looked at and provided an enlarged view of Fig. 1. Fig 1 also illustrates the various configurations of barbs 20. Applicants have drawn similar extension lines, dashed in red for the Examiner's convenience. Here, these lines show that again, none of the barbs intercept the proximal end of the projection, and none are oriented in the longitudinal direction. Specifically, Fig. 1 fails to show barbs having a sharp edge which is (1) oriented in the longitudinal direction and (2) which extends from the proximal end of the projection. While some barbs appear to define or overlap the distal end of the barb, however, in any case, at least two requirements recited in independent claim 1 and at least one requirement of independent claim 13 are not found in Fig. 1.

Accordingly, Applicants respectfully note that the combination of Kingsford and Allen fails to teach the claimed invention. Further, the microneedles resulting from this combination

¹ Office Action, p. 3, ll. 4-5.

fail to provide the benefit required by independent claims 1, 13, and the claims dependent therefrom – specifically, that the microneedles more easily penetrate the stratum corneum layer of the skin. To the contrary, the barbs on the Allen projections “are configured ... to resist removal of the skin attachment member from skin.”² Accordingly, Applicants respectfully request the rejection over Allen in view of Kingsford be reconsidered and withdrawn.

Claims 1-7, 13-19 and 25-27 are rejected under 35 USC §103(a) over Allen et al. in view of Eicher et al. (WO 97/03718) (citing Fig. 3D and the entire reference).³ Eicher et al. suffers from the same deficiency as Kingsford. Specifically, the barbs of Eicher et al. fail to intercept the proximal end of the projections. Again, an enlarged view of Fig. 3D, showing the angle in a red dashed line is included for the Examiner’s convenience.

Accordingly, the teaching of Eicher et al. fails to disclose 1) an edge oriented in the longitudinal direction, and 2) which extends from a proximal end of the microneedle (emphasis again added).⁴ Eicher is cumulative with the teachings of Kingsford and suffers from the same deficiencies. Eicher in combination with Allen (or Kingsford and Allen) still fails to teach at least two requirements of the claimed invention. Accordingly, Applicants respectfully request the rejection over Allen in view of Eicher be reconsidered and withdrawn.

Claim 29 is objected to as being dependent upon a rejected base claim. Claim 29 is amended to be in independent form, as suggested by the Examiner.

The claims are rejected for obviousness-type double patenting over common assigned U.S. Pat. No. 6,652,478 (Gartstein et al.) in view of U.S. Pat. No. 6,334,856 (Allen et al.). Confirming the telephonic interview of Oct. 21, 2004 with Examiner DeSanto, Applicants previously submitted a Terminal Disclaimer in this matter. It is believed this Terminal Disclaimer was not entered in the file. Accordingly, Applicants respectfully resubmit the Terminal Disclaimer and, accordingly, respectfully request reconsideration and withdrawal of the double patenting rejection.

² Abstract, ll. 4-5.


³ Office Action, p. 4, l. 2.

⁴ While one could interpret the entire base as being the proximal end of the microneedle, such an interpretation leads to nonsensical results. For example, referring to Fig. 1 of Kingsford, the extension lines drawn by Applicant show that such an interpretation would have the proximal end of one microneedle overlapping the proximal end of adjacent microneedles – leading to an impossibility. Kingsford teaches the projections are discrete.

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Respectfully Submitted,

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